JUL - 2 2002

510(k) Summary

K021829

1. Company Identification

Eastman Kodak Company
343 State Street
Rochester, NY 14650
585-724-5910

2. Contact Person

Carol C. Ryerson
Regulatory & Clinical Affairs Manager

3. 510(k) Summary Preparation Date

May 31, 2002

4. Device Name

Kodak DirectView CR Long-Length Imaging System

5. Device Classification

Class II

6. Intended Use

The KODAK DirectView CR Long-Length Imaging System is used with the KODAK DirectView CR 800/ CR 900 Systems which are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications. The Long Length Imaging feature is used for examinations of long areas of anatomy such as the leg and spine.

7. Description of Device

The Kodak DirectView CR Long-Length Imaging System extends the capability of the Kodak CR 800 and CR 900 computed radiography systems to allow the capture of long length images with an image area up to 130 cm high x 43 cm wide. Individual CR images are limited to the size of a CR cassette, the largest being 35 x 43 cm. The Kodak Long-Length Imaging System includes a vertical cassette holder, which can hold up to four CR screens and image stitching software, which will operate on the CR 800 or CR 900 system. Image capture is accomplished using standard x-ray equipment and technique. The CR screens are

then removed form the vertical cassette holder and placed in the CR 800 or CR 900 system to be scanned. The image stitching software processes the images correcting for magnification, translation, and rotation differences among the images, eliminates redundant pixels in the overlap region and stitches together the individual images. The resulting single composite image covers an image area of up to 130 cm x 43 cm, and can be stored to a PACS workstation or printed to film using a laser imager.

8. Substantial Equivalence

The Kodak DirectView CR 800/ 900 System is being modified with addition of a software module (Kodak DirectView CR Long-Length Imaging Software) and hardware accessory (Kodak DirectView CR Long-Length Vertical Cassette Holder) to be used with the software. The purpose of these modifications is to enable the use of multiple cassettes to obtain images of long areas of anatomy, up to 130 cm in length, and then to present the image as a single composite image. The CR cassettes and the radiographic techniques remain unchanged. The intended use of the Kodak DirectView CR 800/ 900, previously stated, as "compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications" remains unchanged. The modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Carol C. Ryerson
Regulatory & Clinical Affairs Manager
Eastman Kodak Company
343 State Street
ROCHESTER NY 14650

AUG 23 2013

Re: K021829
Trade/Device Name: Kodak DirectView CR Long-Length Imaging Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 31, 2002
Received: June 4, 2002

Dear Ms. Ryerson:

This letter corrects our substantially equivalent letter of July 2, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

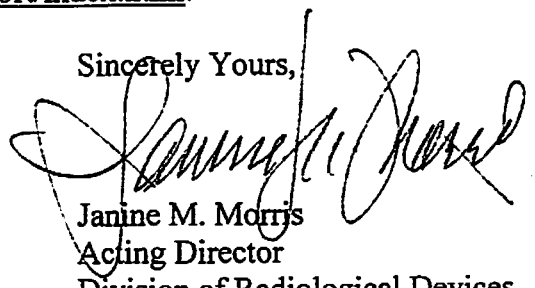
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K021829

Device Name: Kodak DirectView CR Long-Length Imaging System

Indications for Use: The KODAK DirectView CR Long-Length Imaging System is used with the KODAK DirectView CR 800/ CR 900 Systems which are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications. The Long-Length Imaging feature is used for examinations of long areas of anatomy such as the leg and spine.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-the counter use_____
(per 21 CFR 801.109)

David G. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021829